



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[30Day-23-0010]**

**Agency Forms Undergoing Paperwork Reduction Act Review**

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "Birth Defects Study To Evaluate Pregnancy exposures (BD-STEPS)" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on March 1, 2022 to obtain comments from the public and affected agencies. CDC received two comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Birth Defects Study To Evaluate Pregnancy exposures (BD-STEPS)

(OMB Control No. 0920-0010, Exp. 2/28/2023) - Revision -

National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

### Background and Brief Description

Birth defects are associated with substantial morbidity and mortality in the United States. About one in every 33 babies is born with a birth defect. Birth defects contributed to more than one million hospital stays in the U.S. in 2013, resulting in \$22.9 billion in hospital costs. Birth defects are the leading cause of infant mortality and the fifth leading cause of loss of potential years of life before age 65. One in five infant deaths is due to birth defects.

For most birth defects, the causes are not known, making prevention efforts challenging to develop. To date, primary preventive measures are available for only a few birth defects. For example, vaccination programs have reduced the incidence of congenital rubella syndrome, Rh hemolytic disease of the newborn can be prevented by appropriate medical practice, and genetic counseling can provide parents with information about the increased risk of Down syndrome associated with advanced maternal age. Perhaps most importantly, folic acid intake before and during pregnancy can prevent many cases of fatal or permanently disabling neural tube defects such as anencephaly and spina bifida.

This continued burden justifies reasonable attempts to reduce the prevalence of birth defects. To help reduce birth

defects among U.S. babies, in 1996 Congress directed the CDC to establish Centers of Excellence for Birth Defects Research and Prevention. The mandate was formalized with passage of the Birth Defects Prevention Act of 1998. This Act amended Section 317C of the Public Health Service Act (42 U.S.C. 247b-4) and authorized CDC to: (1) collect, analyze, and make available data on birth defects; (2) operate regional centers that will conduct applied epidemiological research for the prevention of birth defects; and (3) provide the public with information on preventing birth defects.

In response to this mandate, the Division of Birth Defects and Infant Disorders (DBDID) obtained OMB clearance for data collection that is carried out by the Centers for Birth Defects Research and Prevention (CBDRP). The CBDRP's first research effort was the National Birth Defects Prevention Study (NBDPS), which began data collection in 1997 and ended in 2013. The CBDRPs transitioned from NBDPS to the Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS), which began data collection in 2014. One of the main activities for each Center is to conduct BD-STEPS in their state, and the purpose of BD-STEPS is to evaluate factors associated with the occurrence of birth defects and stillbirths, and ultimately to work to prevent major birth defects and stillbirths associated with maternal risk factors.

CDC requests OMB approval for an estimated 4,473 annual burden hours. There is no cost to respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Mothers (Interview)	Core Computer Assisted Telephone Interview	3,030	1	55/60
Mothers (Consent)	Linkage to Reportable Infectious Disease Consent	2,590	1	15/60
Mothers (Consent for Residual Newborn Bloodspot Retrieval)	Residual Newborn Bloodspot Consent	1,850	1	15/60
Mothers (Online Questionnaire)	Online Occupational Questionnaire	830	1	20/60
Mothers of AR/MA Stillbirths and Controls (Interview)	Supplemental Computer Assisted Telephone Interview	640	1	25/60
Mothers of AR/MA Stillbirths with Specimens available for Testing	Authorization Form for Stillbirth COVID-19 Sub-Study	157	1	15/60

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